DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 1999

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Roger W. Barnes, Ltd.
342 Sunset Bay Road
Hot Springs, Arkansas 71913

RE: Docket No. 98A-0974

Dear Mr. Barnes:

This is in response to your request for an advisory opinion regarding the agency's interpretation of the exemption from premarket notification (510(k)) requirements provided by Title 21 Code of Federal Regulations (CFR) 807.85(b), and whether that exemption extends to contract manufacturers that label and distribute the product under their own name.

The exemption from 510(k) requirements is limited to a distributor and/or repackager who places a device in commercial distribution for the first time, under their own name, without changing any other labeling, or affecting the device in any other way. The two situations you described in your request involve a person who distributes a medical device manufactured by another company and also manufacturers the same device under contract to that company. The act of distributing the device in the normal course of business does not, by itself, affect the device, other than to move the device along in the chain of commercial distribution. The act of manufacturing, however, does directly affect the device, and clearly is an act other than that of distributing or repackaging a device. Therefore, a contract manufacturer does not qualify for the exemption from premarket notification. This means that a manufacturer cannot be both a private label distributor or repackager and a contract manufacturer without obtaining its own 510(k) for the device prior to the commercial distribution of the device under its own name.

While it is true that the regulation does not expressly state that a contract manufacturer may not qualify for the distributor exemption, the regulation describes precisely the activity that is exempt from premarket notification requirements. That activity is distribution only; the regulation does not authorize an exemption for any other activity. To broaden the exemption to satisfy your request would require amending the regulation. Accordingly, we cannot grant your first request to reverse our position that an alternate manufacturer cannot also be exempt from 510(k) requirements as a distributor of the device manufactured for another.

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Your second request focuses on the use of labeling provisions in sections 801.1(c) and (d), and apparently suggests that compliance with those requirements may support exemption from 510(k) requirements for an affiliated manufacturer. The agency does not agree with this interpretation.

The labeling requirements of section 801 establish minimal requirements to prevent the use of false and misleading information concerning a device. The labeling information required by 801.1(c) and (d) concern statements of fact that must appear on a label to reflect particular situations to provide necessary information to consumers. These labeling requirements do not and never were intended to limit the operation of the device registration, listing, and premarket notification requirements. Accordingly, compliance with section 801.1 (c) and (d) does not relieve a manufacturer of the obligation to comply with premarket notification requirements under section 510 of the act.

If you have additional questions regarding this matter, you may contact Mr. Wally Pellerite, Assistant to the Director, in our Office of Compliance at (301) 594-4692.

Sincerely yours,

Linda Kahan

Linda Kahan
Deputy Director for Policy
Center for Devices and
Radiological Health